

### **REMARKS**

In response to Applicants' previous election dated October 17, 2003, the Examiner has determined that Claims 1-4, 6, 14, 19, 21, 24, 30, 37, 39, 43, 46-50, 52-53, 55 and 58 correspond and read on the elected species. All non-corresponding claims have been withdrawn from further consideration. Applicants understand that should any generic claims be finally held allowable, then the species of the withdrawn claims will be considered allowable as well.

Of the elected claims, the Examiner has initially rejected Claims 1, 39, 47, and 53 as anticipated by U.S. Patent No. 6,461,323 to Fowler et al. under 35 U.S.C. 102(e). Claims 2-3, 19, 30, 43, 48-50 and 53 have been initially rejected as unpatentable over Fowler et al. under 35 U.S.C. 103(a). Claims 4 and 50 stand further rejected under 103(a) as unpatentable over Fowler et al. in view of U.S. Patent No. 6,551,280 to Knighton et al. Claims 6, 14, 21, 24, 37, 46, 52, 55 and 58 stand currently rejected as unpatentable to Fowler et al. in view of U.S. Patent No. 6,454,789 to Chen et al. under 103(a). Finally, Claims 6, 21, 52 and 55 have been further rejected as unpatentable over Fowler et al. in view of U.S. Patent No. 6,106,494 to Saravia et al. under 103(a). No claims have been indicated as allowable.

Additionally, the Examiner has objected to certain informalities in the drawings, the specification, and the claims. Accordingly, a proposed drawing correction is attached hereto. Specifically, the proposed change is directed to the two occurrences of reference number "54" in FIG. 6. The leftmost occurrence—the fuel reactant flow barrier—has been changed to "54a" while the rightmost occurrence—the oxidant reactant flow barrier—has been changed to "54b." Approval of these proposed changes is earnestly sought.

With respect to the specification, the requested changes have been made as presumed by the Examiner, with the exception of the recitation of "electrical contacts 48" on page 9, line 6. Each cited informal occurrence was the result of a typographical error, and was made without any deceptive intent. The excepted reference has been amended to read "electric contacts 48

(similar to electric leads 28 illustrated in FIGURE 1).” No new matter has been added as a result of these specification and drawing changes.

### 35 U.S.C. 102(e) Rejections

The Examiner has rejected Claims 1, 39, 47 and 53 as anticipated by the Fowler et al. reference. The Examiner has stated that:

“Fowler et al. teach tubing 23, 25 (corresponding to the claimed lineset) having a first end capable of attachment to a bag 18 (corresponding to the claimed reservoir) and a second end capable of attachment to a control valve 32 (corresponding to the claimed another component); a pump 20, preferably disposable (see column 4, line 17), for engaging the tubing and controlling a fluid flow through the tubing; batteries 7 (corresponding to the claimed power supply) affixed to other than the pump 20 and capable of operative connection with the pump.” [Emphasis added].

The Examiner has also observed that “Fowler et al. teach that the batteries are disposable.”

With respect to the rejected claims, the Applicants respectfully disagree with the Examiner’s characterization of Fowler et al. First, the Fowler et al. patent is directed to a controlled pump used to supply pressurized irrigation fluid (e.g., sterilized water) to a surgical site. Fowler et al. utilize no lineset, but only a length of tubing to deliver fluid. Further, while it is an important tool in any surgical procedure, the criticality of the automatic pressurized irrigation pump is significantly less than that of the drug infusion system and lineset. It is this criticality to the user (i.e., patient) that has driven the present invention. That is, with each lineset a fresh power supply is made available. The danger of a dead battery halfway through an infusion process is virtually eliminated.

Second, Fowler et al. disclose an automatic pump system which is disposable (Col. 3, lines 62-63). In fact, the pump itself is disposable, not durable (Col. 4, line 17). The disposable nature of the batteries, as referred to by the Examiner, is irrelevant to the present independent claims. Finally, the batteries are not affixed to a component of the system. Rather, they contact electrodes within a housing 84 as a means of supplying power to the system. The Fowler et al.

patent contains no teaching to affix the batteries to a component of the system, only that they are placed into a battery case—i.e., housing 84 (see Fig. 3C). In fact, as the battery housing 84 is merely a part of the power supply, the batteries are unattached to any component. As part of the power supply, the battery housing 84 is disclosed as being attached only to the pump.

Each of Claims 1, 39, 47 and 53 require, as the Examiner has undoubtedly concluded, “a power supply affixed to a component of the infusion system other than the durable pump component”—the amendments to Claims 1 and 47 have been made to clarify this point by adding the underlined text. Claim 39 already includes such clarifying text, while Claim 53 differs only in that it specifically requires the power supply to be attached to the tubing. Support for this limitation is discussed at page 6, lines 29-34, and illustrated in Figures 1-5. The text states “power supply 14 may be attached directly to the tubing surface via connector 34 (dashed power supply 14) or indirectly to the tubing surface, or it may be attached to another component of the system 10.” [Emphasis added].

The Merriam-Webster dictionary defines the term “affix” as “to attach physically” or “fasten to.” The disclosure of the invention supports this definition of the term and the definition is, of course, not repugnant to the ordinary or customary meaning of the term. Therefore, the involved claims each require not only a power supply, but also a physical attachment of the power supply to a component of the system other than the pump.

Clearly, Fowler et al. do not meet the necessary requirements for anticipation of Claims 1, 39, 47 and 53. Fowler et al. fail to disclose (1) a medical infusion lineset; (2) a durable pump component; and (3) a power supply affixed (physically attached) to a component of the infusion system. Each of these limitations is a necessary component of the rejected claims. Instead, Fowler et al. teach the use of (1) a length of tubing which connects to (2) a disposable fluid pump having (3) a plurality of AA batteries secured within a housing that is part of a pump.

In order for a reference to act as a § 102 bar to patentability, the reference must teach each and every element of the claimed invention. Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771 (Fed. Cir. 1983). Without the required teaching of “each and every element” as set

forth in the claims, it is improper for the Examiner to continue such rejections under §102. Accordingly, because Fowler et al. does not provide the necessary teaching of each and every element of the rejected claims, the Examiner's current rejection under 35 U.S.C. 102(e) is not supportable. Reconsideration is respectfully requested.

### 35 U.S.C. 103(a) Rejections

Of the non-withdrawn claims, the Examiner has also rejected (in summary) Claims 2-4, 6, 14, 19, 21, 24, 30, 37, 43, 46, 48-50, 52, 53, 55, and 58 as unpatentable over Fowler et al. in view of several other references (see previous recitation of specific rejections). Primary to all rejections was the Examiner's use of the Fowler et al. reference. Of these claims, only Claims 19 and 30 are independent and not previously addressed.

Claims 19 and 30 both require a power supply attached to the tubing of the lineset. Fowler et al. arguably do not disclose attachment of the power supply to any system component. At best, Fowler et al. may be considered to teach placement of batteries into a housing on a fluid pump—a concept which is neither new nor inventive. Further, such a teaching does not render the present claims obvious. The present claims are clear—the power supply is attached to the tubing of the lineset.

This distinction is not without significance. The tubing of the lineset is much less expensive than a fluid pump. By only disposing of the tubing with the power supply, the durable components of the pump—or any other electrical component—are saved for further use. The result is a significant financial saving on pump components, but with the continued benefit of having a reliable power supply for each medical procedure.

The Knighton et al. patent is directed to a therapeutic device and system which provides support and pressure to patient tissue to, for example, treat diseases and injuries and speed the healing. The disclosed device employs a foam material which in a relaxed state applies pressure to an injured site, such as a sprain, strain, or bone break. The device may be implanted in the patient, such as for use as a penile implant, or worn externally, such as for use as a bone cast.

However, Knighton et al. do not disclose a medical lineset, nor do they disclose attaching a power supply to a component of the system other than the air pump (vacuum) employed to create an evacuated state in the foam. Knighton et al. most certainly do not disclose attaching a power supply to the tubing of the system, as required by claims of the present application.

The Chen et al. patent is directed to a portable device for photodynamic therapy. The disclosed device has a light source which when implanted within the patient is used to administer photodynamic therapy. A balloon is also employed to facilitate the process by holding the light source in place. However, Chen et al. do not disclose a medical lineset, or infusion system, or method for delivering fluid using a lineset, as required by claims of the present application.

The Saravia et al. patent is directed to a self-contained fluid management pump for surgical procedures. Saravia et al. specifically state that the disclosed invention utilizes a "power pack 26 that is attached to and extends below the pump." (Col. 4, lines 33-35). As with Fowler et al., Saravia et al.—which, like Fowler et al., is also a surgical irrigation system—does not disclose attaching a power supply to a component of the system other than the pump employed to force fluid to the surgical site. Saravia et al. most certainly do not disclose attaching a power supply to the tubing of the system, as required by claims of the present application.

In order to support a conclusion that a claim is directed to obvious subject matter, the cited references must impliedly suggest the invention *described by the claim*, or the Examiner must present a convincing line of reasoning as to why an artisan would have found *the claimed invention* obvious in light of the teachings of the cited references. See Ex Parte Clapp, 227 U.S.P.Q. 972 (PTO Bd. App. 1985). "[T]he mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification." In re Laskowski et. al., 10 U.S.P.Q. 2d 1397, 1398, (Fed. Cir. 1989), citing, In re Gordon, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). In discussing the mandate of 35 U.S.C. §103, the Federal Circuit holds "it is the invention as a whole that must be considered in obviousness determinations. The invention as a whole embraces the structure, its properties *and*

*the problem it solves.*"[Emphasis added]. In re Wright, 6 U.S.P.Q. 2d 1959 (Fed. Cir. 1988). It is not enough to just find components in the prior art, as the Examiner has done here.

On that point, the Federal Circuit has noted:

[I]t is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious . . . [o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.

*In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992).

Unless the references suggest the particular combination themselves, they cannot show the actual invention was obvious. *In re Mahurkar Patent Litigation*, 831 F.Supp. 1354, 1374, 28 USPQ2d 1801, 1817 (N.D. Ill. 1993). The decomposition of an invention "into its constituent elements, finding each element in the prior art, and then claiming that it is easy to reassemble these elements into the invention, is a forbidden *ex post* analysis." *Id.*

In the present case the Examiner has merely provided the "forbidden *ex post* analysis" by piecing together two references disclosing constituent elements of the present invention without any motivation to do so—other than that provided by the present application. The Examiner has given no weight to the claimed limitation of affixing the power supply to other than the durable pump component of the system, and more specifically to the tubing of the lineset or system, though each such recitation individually distinguishes the present invention over the prior art.

The Examiner has given no thought to how one might combine the teaching of Fowler et al. (an irrigation system for surgical procedures), with the teaching of Knighton et al. (a therapeutic foam device for tissue support and pressure), or Chen et al. (an implantable photodynamic therapy system) to accomplish the invention of this application. The inventions of these references are directed to solve very different problems in very different fields related to medical devices and procedures. Instead, the Examiner has merely referenced component elements which are, at best, only discussed in one of the cited references. Components or limitations which were not discussed by the references were given no weight by the Examiner.

Accordingly, the Applicants traverse the Examiner's combination of the cited references to reject the pending claims. Reconsideration and withdrawal of all rejections in light of the amendments and remarks is respectfully requested.

All the remaining claims are dependent upon one of independent Claims 1, 19, 30, 39, 47, and 53. Each dependent claim merely adds a further limitation to the independent claim from which it depends. As each independent claim is in condition for allowance, the dependent claims should likewise be considered allowable. Accordingly, reconsideration is respectfully requested and a notice to that effect is earnestly sought at the examiner's earliest convenience.

Applicants request that the remaining non-elected claims, Claims 5, 7-13, 15-18, 20, 22, 23, 25-29, 31-36, 38, 40-42, 44, 45, 51, 54, 56 and 57, be withdrawn from consideration without prejudice.

### CONCLUSION

Claims 1-58 are currently pending in the present application. Of these, Claims 5, 7-13, 15-18, 20, 22, 23, 25-29, 31-36, 38, 40-42, 44, 45, 51, 54, 56 and 57 have been withdrawn as directed to a non-elected species, leaving Claims 1-4, 6, 14, 19, 21, 24, 30, 37, 39, 43, 46-50, 52-53, 55 and 58 for examination. The Examiner has initially rejected all claims under 35 U.S.C. 102, 103, and 112. Applicants have amended Claims 1, 47 and 52 to clarify matters where necessary. In light of the amendments and the above-remarks, Applicants believe all considered claims are now in condition for allowance. Reconsideration of these claims is respectfully requested. Applicants understand that should any generic claims be finally held allowable, then the species of the withdrawn claims will be considered allowable as well.

If it would expedite the progress of this Application through the examination process, the Examiner is authorized to call the undersigned attorney.

Respectfully submitted,

Dated: March 2, 2004

By: 

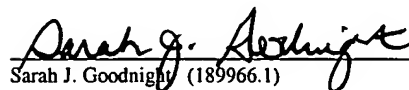
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Date of Deposit: March 2, 2004

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